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*Proposed Regulation/Guidance Document:*

**FDA Draft Guidance for Industry: “Field Alert Report Submission: Questions and Answers.”
Docket No. FDA-2018-D-2326**

Comments from: ISPE (International Society for Pharmaceutical Engineering)

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| **GENERAL COMMENTS ON THE DOCUMENT** |
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| Add rows as needed |

**Specific Comments on the Text**

ISPE indicates text proposed for deletion with ~~strikethrough~~ and text proposed for addition with **bold and underlining**.

| **Line Number** | **Current Text** | **Proposed Change** | **Rationale or Comment** |
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